REMARKS

Telephone Interview:

A telephone interview was conducted on October 7, 2003, among Examiner Davis, Examiner Lankford, Angela Dallas Sebor, Michael Tompkins, and Bill Barclay. The courtesy extended by the Examiners to the representatives for Applicant was greatly appreciated. During the interview, remaining issues under 35 U.S.C. § 103 were discussed.

During the telephone interview, the Examiners asked for clarification as to how the claimed process does not read on, for example, a laboratory process whereby microbial cells are lysed and then centrifuged. For example, the Examiner confirmed that the "laboratory process" could be a conventional process where a culture of microbial cells is lysed and then the soluble extract collected by centrifugation for various purposes such as purification of a soluble protein, enzyme assay and the like.

It was explained to the Examiners during the interview that the claimed process, while it can include the two basic steps of lysing microbial cells and centrifuging, also includes additional specific steps that are necessary to recover lipids from the microorganism. It is not believed that the alleged prior art teaches these additional steps and the process of using phase separation to specifically recover lipids from a microorganism in the substantial absence of an organic solvent, followed by the steps of actually recovering the separated lipids. Moreover, simply centrifuging a lysed microorganism without any other steps would not allow one to practice the claimed method.

More specifically, the claimed method requires (in step (b)) treating the lysed cell mixture using an extraction process conducted in a medium that comprises less than about 5% of an organic solvent to produce a heavy layer and a light layer, wherein the heavy layer comprises an aqueous phase and the light layer comprises said lipid. In a simple lysis and centrifugation referenced by the Examiners, microbial cells are lysed and centrifugation yields a solid pellet (containing cell wall components, membrane components, and insoluble components) and a liquid phase that contains aqueous components, lipid components and soluble proteins. When a cell is lysed, the presence of proteins in the lysate stabilizes an emulsion that is formed between the lipids and other components, and the lipids therefore do not substantially separate from the rest of the aqueous phase. Therefore, centrifugation of lysed cells fails to produce a heavy layer comprising an aqueous phase and a light

layer comprising the lipids. In order to effectively separate the lipids from the aqueous phase, one conventionally uses solvent extraction with an organic solvent, which presents many problems for the subsequent purification and usefulness of the lipids in a commercial product. The present invention provides a solution to this problem by teaching a method in which the use of an organic solvent is not required to separate lipids from a microbial cell.

In contrast, the present invention uses a process to break an emulsion between the lipids and other cellular products and to produce the claimed heavy and light layers without the need for organic solvent extraction to obtain the lipids. This method generally involves removing or denaturing proteins so that the emulsion formed between lipids and aqueous components is broken and the claimed layers can form. As discussed in the specification, this step of treating the lysed cell mixture can be performed in various ways, including by adding a base to hydrolyse at least a portion of the proteinaceous compounds in the lysate (e.g., page 7, lines 4-10), by heating the mixture to denature proteins and solubilize organic materials (e.g., page 7, lines 21-22), and/or by repeated washing steps with an aqueous solution until a substantially non-emulsified lipid layer is obtained (e.g., page 8, lines 8-22). Once the step of treating the lysed cells enables the formation of the light layer comprising the lipids, the additional steps of separating the layers and recovering the lipids can be performed. While centrifugation can be used to perform this separation, it is not required, since once the lipids are substantially non-emulsified, the separation will occur naturally over time.

The discussion above is provided at the request of the Examiners during the October 7 interview and is intended to explain more specifically how the claimed invention is distinguished from the prior art. It is believed that the Examiners were persuaded by the arguments presented in the October 7 telephone interview and that this discussion will clarify the issues for the record.

Rejection of Claims 1-6, 14, 47-56 and 58 Under 35 U.S.C. § 103:

The Examiner has rejected Claims 1-6, 14, 47-56 and 58 under 35 U.S.C. § 103, contending that these claims are unpatentable over Gudin. Specifically, the Examiner admits that Gudin does not teach an emulsified lipid solution which becomes substantially non-emulsified, but contends that Gudin teaches the separation of a solid phase from a liquid phase and therefore contends that for the

reasons of record, one would have been motivated by Gudin to centrifuge microorganisms in a solventless extraction process to successfully obtain lipids.

This rejection is respectfully traversed. As discussed in the prior responses of record, Gudin does not teach or suggest the claimed process. Moreover, even if Gudin teaches a step of lysing and centrifuging cells, as discussed in detail above and during the interview of October 7, these steps are not sufficient to enable the recovery of lipids and will not meet the limitations of the claimed method.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claims 1-6, 14, 47-56 and 58 under 35 U.S.C. § 103.

Rejection of Claims 1-10, 12-19, 47-56 and 58 Under 35 U.S.C. § 103:

The Examiner has rejected Claims 1-10, 12-19, 47-56 and 58 under 35 U.S.C. § 103, contending that these claims are unpatentable over Gudin in view of Barclay. This rejection is made for the reasons set forth in the first rejection under § 103 above and for the reasons of record.

The rejection of Claims 1-10, 12-19, 47-56 and 58 under 35 U.S.C. § 103 is respectfully traversed. For the reasons discussed above and during the telephone interview of October 7, it is submitted that Gudin does not teach or suggest the claimed method. Moreover, the teachings of Barclay when combined with Gudin do not make up for the deficiencies of Gudin.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claims 1-10, 12-19, 47-56 and 58 under 35 U.S.C. § 103.

Rejection of Claims 1-9, 11, 14, 47-56 and 58 Under 35 U.S.C. § 103:

The Examiner has rejected Claims 1-9, 11, 14, 47-56 and 58 under 35 U.S.C. § 103, contending that these claims are unpatentable over Gudin in view of Wagner. This rejection is made for the reasons set forth in the first rejection under § 103 above and for the reasons of record.

The rejection of Claims 1-9, 11, 14, 47-56 and 58 under 35 U.S.C. § 103 is respectfully traversed. For the reasons discussed above and during the telephone interview of October 7, it is submitted that Gudin does not teach or suggest the claimed method. Moreover, the teachings of Wagner when combined with Gudin do not make up for the deficiencies of Gudin.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claims 1-9, 11, 14, 47-56 and 58 under 35 U.S.C. § 103.

It is submitted that the claims are in a condition for allowance. In the event that the Examiner has any further concerns or questions regarding the claims, she is encouraged to contact the below-named agent at (303)863-9700.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Angela Sebor

Angela Dallas Sebor
Registration No. 42,460
1560 Broadway, Suite 1200
Denver, CO 80202-5141
(303) 863-9700

Date: October 15, 2003